

K101425

510(k) Summary

SEP 10 2010

510(k) Submission Information:

Device Manufacturer: Siemens Healthcare Diagnostics
Contact name: Elisabeth Warriner, Regulatory Technical Specialist
Fax: 916-374-3144
Date prepared: August 31, 2010
Product Name: Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name: MicroScan Dried Gram-Negative MIC/Combo Panels
Intended Use: To determine antimicrobial agent susceptibility
510(k) Notification: New antimicrobial - Doripenem
Predicate device: MicroScan Dried Gram-Negative MIC/Combo Panels –
Ertapenem (K032706)

510(k) Summary:

MicroScan Dried Gram-Negative MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-negative bacilli.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in broth and dehydrated. Various antimicrobial agents are diluted in broth to concentrations bridging the range of clinical interest. Panels are rehydrated with water after inoculation with a standardized suspension of the organism. After incubation in a non-CO₂ incubator for 16-20 hours, the minimum inhibitory concentration (MIC) for the test organism is read by determining the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan Dried Gram-Negative MIC/Combo Panel demonstrated substantially equivalent performance when compared with an CLSI frozen Reference Panel, as defined in the FDA document "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", dated August 28, 2009. The Premarket Notification (510[k]) presents data in support of the MicroScan Dried Gram-Negative MIC/Combo Panel with Doripenem.

The external evaluation was conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed Dried Gram-Negative Panel by comparing its performance with a CLSI frozen Reference panel. Challenge strains were compared to Expected Results determined prior to the evaluation. The Dried Gram-Negative Panel demonstrated acceptable performance with an overall Essential Agreement of 97.0% for Doripenem when compared with the frozen Reference panel.

Inoculum and instrument reproducibility testing demonstrated acceptable reproducibility and precision with Doripenem, regardless of which inoculum method (i.e., Turbidity and Prompt™), or instrument (autoSCAN®-4 and WalkAway®) was used.

Quality Control testing demonstrated acceptable results for Doripenem.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics Inc.
c/o Ms. Eliabeth Warriner
Regulatory Technical Specialist
1584 Enterprise Blvd.
West Sacramento, CA 95691

SEP 10 2010

Re: K101425

Trade/Device Name: MicroScan Dried Gram-Negative MIC/Combo Panels with
Doripenem (0.008-32ug/mL)

Regulation Number: 21 CFR 866.1640

Regulation Name: Antimicrobial Susceptibility Test Powder

Regulatory Class: Class II

Product Code: LRG, JWY, LTT

Dated: September 9, 2010

Received: September 10, 2010

Dear Ms. Warriner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

Page 2 – Ms. Eliabeth Warriner

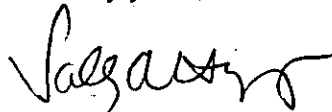
medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101425

SEP 10 2010

Indications for Use

510(k) Number (if known): K101425

Device Name: MicroScan® Dried Gram-Negative MIC/Combo Panels with Doripenem (0.008 – 32 mcg/ml)

Indications For Use:

The MicroScan® Dried Gram-Negative MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-negative bacilli. After inoculation, panels are incubated for 16 – 20 hours at 35°C +/- 1°C in a non-CO2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for the addition of the antimicrobial Doripenem at concentrations of 0.008 to 32 mcg/ml to the test panel.

The gram-negative organisms which may be used for Doripenem susceptibility testing in this panel are:

Acinetobacter baumannii
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostic Devices (OIVD)

Judith E. Cooke

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101425